MAY 0 9 2002

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510(k) Summary of Safety and Effectiveness

Date: April 8, 2002

Submitter: GE Medical Systems *Information Technologies*
61 Barnes Park Road North
Wallingford, CT 06492 USA

Contact Person: Joelle Neider
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 203-949-8232
Fax: 414-918-8113

Device: Trade Name: Corometrics Model 2120is Maternal/Fetal Monitor

Common/Usual Name: Maternal/Fetal Monitor

Classification Names: 21 CFR 884.2740 System, Monitoring, Perinatal

Predicate Devices: K012718 Corometrics Model 2120is Maternal/Fetal Monitor

K990966 Masimo SET® 2000 Pulse Oximeter and LNOP® series of sensors and cables

Device Description: The 2120is Maternal/Fetal Monitoring System consists of the following features/options that can be available in multiple configurations:

- fetal heart rate (via Doppler Ultrasound of FECG)
- maternal uterine activity (via intrauterine pressure catheter or tocotransducer
- fetal movement detection
- maternal non-invasive blood pressure (clinician prompted or automatic)
- maternal pulse oximetry
- maternal heart/pulse rate (MECG) and ECG waveform "snapshot"

The 2120*is* is a full-featured maternal/fetal monitor. The device is also capable of providing bed-to-bed surveillance when multiple 2120*is* monitors are connected via an Ethernet network. The monitor is also capable of acting as a bedside terminal to the QS system. In this capacity, the 2120*is* monitor provides the features of a standard PC QS bedside terminal.

Intended Use: The 2120is Maternal/Fetal Monitoring System is intended for monitoring fetal and maternal vital signs: fetal heart rate; fetal heart rate high/low/poor signal quality alarms; maternal uterine activity; heart/pulse rate, blood pressure, nondiagnostic maternal ECG and %SpO_2. Optional fetal movement detection is available.

Technology: The Corometrics Model 2120is Maternal/Fetal Monitor employs the same fundamental scientific technology as the predicate devices.

Test Summary: The Model 2120*is* Maternal/Fetal Monitor complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Model 2120*is*:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the Model 2120is Maternal/Fetal Monitor (with Masimo SET Pulse Oximetry) is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Mr. Joelle Neider
Corporate Regulatory Affairs
GE Medical Systems
Information Technologies
61 Barnes Park Road North
P.O. Box 333
WALLINGFORD CT 06492-0333

Re: K021135
Trade/Device Name: Corometrics Model 2120is Maternal/Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: April 8, 2002
Received: April 9, 2002

Dear Mr. Neider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

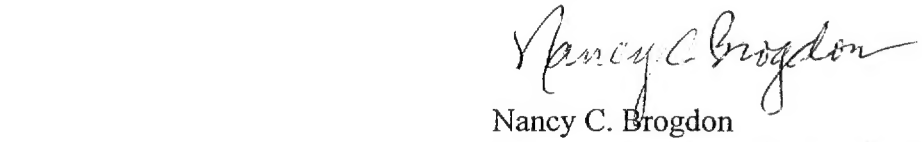
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): 510(k) filed on April 8, 2002

Device Name: Corometrics Model 2120*is* Maternal/Fetal Monitoring System

Indications For Use:

I. Fetal Surveillance

A Corometrics 2120*is* Maternal/Fetal Monitoring System is used for non-invasive and invasive monitoring of the fetus during the antepartum period as well as throughout labor and delivery (i.e. fetal heart rate and uterine activity monitoring). Fetal movement detection and fetal heart rate alarm options (user selectable high/low and poor signal quality alarms) are available.

II Maternal Monitoring

A Corometrics 2120*is* Maternal/Fetal Monitoring System is intended for monitoring maternal vital signs to help assess maternal well-being. The vital signs which can be measured with these monitor configurations are summarized as follows:

NOTE: Maternal vital signs provided by the monitor should only be used as an adjunct in patient assessment in conjunction with clinical signs and symptoms.

Blood Pressure: The monitor is intended for use in the non-invasive monitoring of maternal blood pressure (NBP). This monitor is not intended for use in the neonatal or pediatric blood pressure monitoring.

Pulse Oximetry. The monitor is intended for use in the non-invasive monitoring of maternal functional oxygen saturation of arterial hemoglobin (MSpO2).

Heart/Pulse Rate. The monitor is intended for use in the non-invasive monitoring of the maternal heart/pulse rate. Additionally, an MECG waveform "snapshot" may be displayed and printed.

NOTE: Only the maximum configuration provides both maternal heart rate and pulse rate data.

Bed-to-bed surveillance is available when 2120*is* Series Monitors are networked together.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021135